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Clinical study of benign endometrial hyperplasia and response of Unani drugs with estimation of serum oestrogen levels

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ABSTRACT

Endometrial Hyperplasia represents a spectrum of irregular morphological alterations, made by abnormal proliferation of the endometrial glands results in an increase in gland to stroma ratio. When compared to endometrium from proliferation phase of the cycle. The proliferation glands in endometrial hyperplasia can vary greatly in size and shape, and cytological atypia may be present. According to Hakeem Ajmal Khan in his book HAZIQ, Hakeem Anwer Ali Khan in his book Taleem-ul Qabela and Hakeem Shafaqat Azmi in his book Amraaz –e- Niswaan said that the Endometrial hyperplasia is caused due to alteration of humors and the temperament of uterus and the increase in retaining power (quwat-e- masika) of uterus is the cause of thickening of inner layer of uterus which leads to warm-e- daroon-e- raham. Objective: To prove the efficacy of Unani medicine in Benign Endometrial Hyperplasia Methodology: The study was carried out in the P.G Department of Qabalath – O – Amraaz – E – Niswaan at Government Nizamia Tibbi College and Hospital, Charminar, Hyderabad. Randomized single blind study with Pre and Post-test evaluation was conducted. Total 40 cases of Endometrial Hyperplasia were selected which is divided into two Groups. Group A – 20 Cases and Group B – 20 Cases. Inclusion Criteria: Age 25Yrs. to 55 Yrs., Only married women, Simple Hyperplasia with cystic without atypia, Complex hyperplasia with adenomatous without atypia, History of irregular menstrual cycles, PCOD's, Hormone replacement therapy (HRT). Exclusion Criteria: Simple Hyperplasia with cystic Atypia, Complex Hyperplasia with Adenomatous Atypia/Carcinoma in Situ, Uterine Fibroids, Uterine Polyps, PID (Pelvic Inflammatory Disease), Systemic Disorders like tuberculosis, heart Diseases, Renal Disorders & Neurological Disorder, Unmarried Women. Drugs which were selected for trial were finalized on the basis of these following properties like Mohalil – e- Aoram, Qhabiz, Musaffi – E – Khoon & Dafae Tafoon were selected for the study. In group A & B drugs given in the form of Joshanda, Sufoof, Humool and Zimaad. Group A- JOSHANDA: Gul – e – Banafsha, Babuna, Tukhm – e – Kataan, Sumbul e Tib, Gul – e – Tisu, Makoh – e – Khuskh, Arjun Chall, Gul – e – Surkh. HUMOOL: Mazo, Gul – e – Surkh, Shib – e – Yamani, Chub Zard, Zulal – e- Tukhme Bartang. SUFOOF: Musli Safaid, Mushtagi, Mochras, Gul – e – Surkh, Maye Kalan. ZIMAAD: Gul- e – Banafsha, Makoh – e – khuskh, Magaz – e – Fuloos – e- Qayashambar, Kashneez – e- Sabz, Tukhme Alsi. Group B – JOSHANDA: Gul – e – Banafsha, Babuna, Tukhm – e – Kataan, Sumbul e Tib, Gul – e – Tisu, Makoh – e – Khuskh, Arjun Chall, Gul – e – Surkh. HUMOOL: Luab – e – Tukhme Alsi, Luab –e- Tukhme Khatmi, Aab – e – Kashneez Sabz, Gul – e- Surkh, Makoh – e – Khushk. SUFOOF: Gul – e – Dhava, Gul- e- Gaozaban, Gul – e- Surkh, Gul – e – Banafsha. ZIMAAD: Gul – e – Tisu, Gul – e – Banafsha, Raswat, Tukhme Alsi, Magz – e – Gheegawar. Results: Group A 8 patients (40%) cured; 7 patients (35%) Partially relieved. Where as in Group B 11 patients (55%) cured and 7 patients (35%) Partially relieved. Conclusion: The study proved efficacy of Unani formulation with good results in Benign Endometrial Hyperplasia with no major side effects.

Keywords: *Beesh Takoon Daroon-E-Reham, Endometrial Hyperplasia, Quwat-e- Masika, Atypia, Mo, halil – e- Aoram, Qhabiz, Musaffi – E – Khoon & Dafae Tafoon, Joshanda, Sufoof, Humool, Zimaad.*

INTRODUCTION

Endometrial Hyperplasia represents a spectrum of irregular morphological alterations, made by abnormal proliferation of the endometrial glands resulting in an increase in gland-to-stroma ratio. When compared to endometrium from proliferation phase of the cycle [1-2]. The proliferation glands in endometrial hyperplasia can vary greatly in size and shape, and cytological atypia may be present [45]. Endometrial hyperplasia may cause endometrial cancer in up to 50% of cases. Endometrial malignancies are the most common gynecological disorder in developing countries. Therefore, a careful search for malignancy particularly in women with multiple risk factors is advised by many researchers in daily practice. With the high rate of endometrial hyperplasia reoccurrence. The careful diagnosis of endometrial hyperplasia is required to give the appropriate treatment and save the patient from the risk of malignancy.

The ancient Unani physician talked about that endometrial hyperplasia is one of the high-risk gynecological disorders that occurs due to changes in AKHLATH (humors), Mizaaj, and QUA-E-JISMANIA and the treatment given according to the alteration in Mizaaj.

According to Hakeem Ajmal Khan in his book HAZIQ [9], mohammed abdul Razzaq in his book Taleem-ul Qabela [25] and Hakeem Shafaqat Azmi in his book Amraaz –e- Niswaan [95] said that the Endometrial hyperplasia is caused due to alteration of touches of humor and the temperament of the uterus and the increase in retaining power (quwat-e- masika) of the uterus is the cause of thickening of the inner layer of the uterus which leads to warm-e- daroon-e- raham.

According to Shaik ur Raees Bu Ali Sina in his book Al-Khanoon

[11], Warm e Reham is a condition in which the temperament of Reham will be altered due to alteration of Humors, i.e Blood, Pleghm, Bile and Melanin and the forces of the uterus in which the discharging force of uterus i.e Quwat e Dafia decreases and the retaining power of Uterus that is QUWAT E MASIKA increases. The disturbance caused the retention of abnormal fluids and waste material resulting in inflammation of the inner-most layer of the uterus. This inflammation is called Warm e Daroon e Reham.

According to Shaik Hakeem Mohammed Kabeeruddin Sahab in his book Al-Akseer [29] explained that the– Warm – e - Reham is a condition which has direct side effects on stomach functions and the Brain. Due to this reason, patients suffer from headaches, Nausea, Indigestion, Neck pain, dull pain in both eyes, etc.

According to Buqraat (Father of medicine), if Warm – e – Reham or Warm e Muqaad is present due to any external cause or trauma, there will be a drippling of urination present due to constriction of the neck of the Urinary Bladder.

According to Ahmed Al Hassan Al Jurjani in his book Zaqeera e Qwazam Shahi [12] and Musanif, Abu al Hasan Ibn e Abbas Al Majoosi in his book Kamil Us Sanaa [13] said that Warm e Reham has been given a classification according to the causes of Warm-e- Raham.

1. Warm E Haar which includes Warm e Damavi and Warm e Safravi.
2. Warm e Barid which includes Warm e Balgami and Saodavi or Sulab.

According to Abu al Hasan Ibn e Abbas Al Majoosi [12] said in his book, Warm e Saodavi is also called "Sequroos".

According to Hakeem Mohammed Azam Khan in his book Ramooz e Azam [5], Mussanif Ahmed Al Hasan Al Jurjani in his book Zaqeera e Qwazam Shahi [12], Hakeem Waseem Ahmed Aazmi in his book Amraaz e Niswaan [15] and Hakeem Rasheed Ashraf Nardi in his book Firdous ul Hikmat Fil Tib [19], explained the causes of Warm – e - Reham.

Causes

1. Absence of Periods for a long time.
2. Excessive Intercourse.
3. Multiple history of Abortion.
4. Any local injury or Trauma to the Uterus.
5. Due to insertion of any harmful chemical or medicine in the uterus.
6. Chronic constipation and Dysentery.
7. Any Psychologic disorder.

MATERIAL AND METHODS

Study Design: A randomized single blind study with Pre and Post-test evaluation was conducted from2017 to 2019 in Post Graduate Dept. of Ilmul Qabalath wa Amraaz – E –Niswan, Government Nizamia Tibbi College and Government Nizamia General Hospital, Charminar, Hyderabad. Ethical clearance certificate obtained from Institutional Ethical Committee.

Sample Size: 40 patients were selected for clinical trial-based selection criteria in the study and divided into 2 groups, Group A and Group B. 20 patients were selected in each group based on Inclusion and Exclusion Criteria. During the trial, 7 patients were irregular in the follow-ups.

Inclusion Criteria: Age 25Yrs. to 55 Yrs., Only married women, Simple Hyperplasia with cystic without atypia, Complex hyperplasia with adenomatous without atypia, History of irregular menstrual cycles, PCOD's, Hormone replacement therapy (HRT).

Exclusion Criteria: Simple Hyperplasia with cystic Atypia, Complex Hyperplasia with Adenomatous Atypia/Carcinoma in Situ, Uterine Fibroids, Uterine Polyps, PID (Pelvic Inflammatory Disease), Systemic Disorders like tuberculosis, heart Diseases, Renal Disorders & Neurological Disorder, Unmarried Women.

Pharmacognosy: Drugs which are selected for trial were finalized based on their efficacy in the management of Benign Endometrial Hyperplasia and their Pharmacological effects (Temperaments & properties), easy availability with no side effects in both Groups. Medicines with the following properties: Mohalil -e- Aoram (Anti Inflammatory), Qhabiz (Astringent), Musaffi – E – Khoon (Blood Purifier), Dafae Tafoon (Anti-Bacterial) were selected for the study.

In Groups a & B Drugs Are Given in the Form of Joshanda, Sufoof, Humool and Zimaad.

GROUP A DRUGS	METHOD OF PREPARATION.
JOSHANDA: Gul – e – Banafsha, Babuna, Tukhm – e – Kataan, Sumbul e Tib, Gul – e – Tisu, Makoh – e – Khuskh, Arjun Chall, Gul – e – Surkh.	Soak the above Drugs in 400ml of water overnight, and boil in the morning till the quantity decreases to 200ml. Filter it and should be taken 100ml twice a day (on an empty stomach Before breakfast and Before Dinner). For 12 days in each cycle. Duration of course is 3-4 months
HUMOOL: Mazo, Gul – e – Surkh, Shib – e – Yamani, Chub Zard, Zulal – e- Tukhme Bartang.	All the drugs were taken into a dry form made into a fine powder and mixed with Roghan-e-Gul. A sterilized cotton gauze with attached thread is soaked in the mixture and kept in the posterior Fornix of the Vagina under strict aseptic precaution. Which is to be removed after 6 to 8 hours. Once in a day for 12 days in each cycle. The duration of the cycle is 3-4 months.
SUFOOF: Musli Safaid, Mushtagi, Mochras, Gul – e – Surkh, Maye Kalan.	All the above drugs are taken and cleaned, then grounded into Fine powder. 10gms is given in the Morning and 10gms the evening before meals. For 12 days in each cycle. The duration of the cycle is 3-4 months.
ZIMAAD: Gul- e – Banafsha, Makoh – e – khuskh, Magaz – e – Fuloos – e- Qayashambar, Kashneez – e- Sabz, Tukhme Alsi.	All the above drugs are taken and cleaned. Then ground into a fine powder and mixed with water. Make a fine paste and apply it to the lower abdominal region. Apply once a day for 12 days in each cycle. The duration of the cycle is 3-4 months.

GROUP B DRUGS	METHOD OF PREPARATION.
JOSHANDA: Gul – e – Banafsha, Babuna, Tukhm – e – Kataan, Sumbul e Tib, Gul – e – Tisu, Makoh – e – Khuskh, Arjun Chall, Gul – e – Surkh.	Soak the above Drugs in 400ml of water overnight, and boil in the morning till the quantity decreases to 200ml. Filter it and should be taken 100ml twice a day (on an empty stomach Before breakfast and Before Dinner). For 12 days in each cycle. The duration of the course is 3-4 months.
HUMOOL: Luab – e – Tukhme Alsi, Luab –e- Tukhme Khatmi, Aab – e – Kashneez Sabz, Gul – e- Surkh, Makoh – e – Khushk.	The above 3 Drugs are soaked in water overnight and filtered in the morning and take extract and mixed with the fine powder of Gul – E – Surkh and Makoh – E – Khushq and make a fine mixture. A sterilized cotton gauze with attached thread is soaked in the mixture and kept in Post fornix of the Vagina under strict aseptic precaution. Which is to be removed after 6 to 8 hours. Once in a day for 12 days in each cycle. The duration of the cycle is 3-4 months.
SUFOOF: Gul – e – Dhava, Gul- e- Gaozaban, Gul – e- Surkh, Gul – e – Banafsha.	All the above drugs in equal quantity are taken and cleaned. Then grinded into a fine powder and given 10 grams in the morning and evening before food for 12 days in each cycle. The duration of the cycle is 3-4 months.
ZIMAAD: Gul – e – Tisu, Gul – e – Banafsha, Raswat, Tukhme Alsi, Magz – e – Gheegawar.	All the above drugs are taken and cleaned then grinded into a fine powder and mixed with the Aloe Vera paste and make a fine paste and applied on the lower abdominal region. Apply once in a day for 12 days in each cycle. The duration of the cycle is 3-4 months.

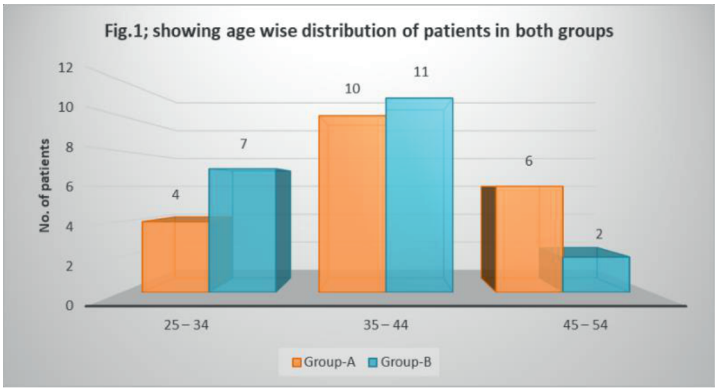
***Follow-up**: Patients were instructed to start Oral Medication on 2nd day of menses for up to 12 days. Internal medication (Humool and Zimaad) was started depending on the day when the bleeding stopped.*

Subjective Parameters: Includes Menstrual bleeding that is heavier or longer lasting than usual, Menstrual cycles (Amount of time between periods) that are shorter than 21 days, Intermenstrual Bleeding and Post-Menopausal Uterine Bleeding.

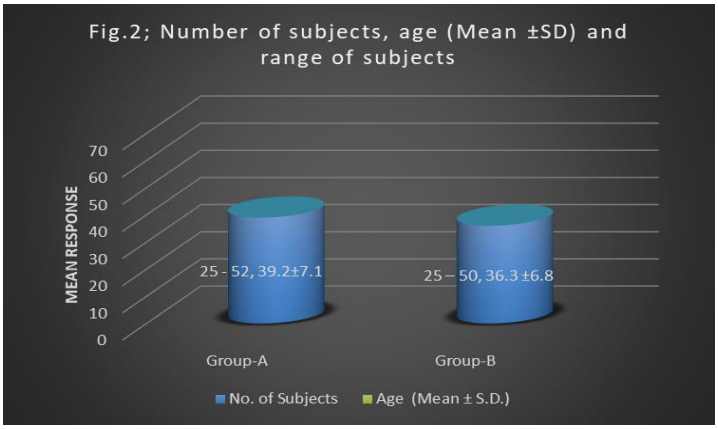
Objective Parameters: Includes routine examinations like CBP, CT, BT, CUE, T3, T4, and TSH, and Special Investigations like USG, Endometrial Biopsy, E2 (Serum Estradial).

The clinical profile and response with Group A and Group B medicine have been discussed as follows with statistical tables.

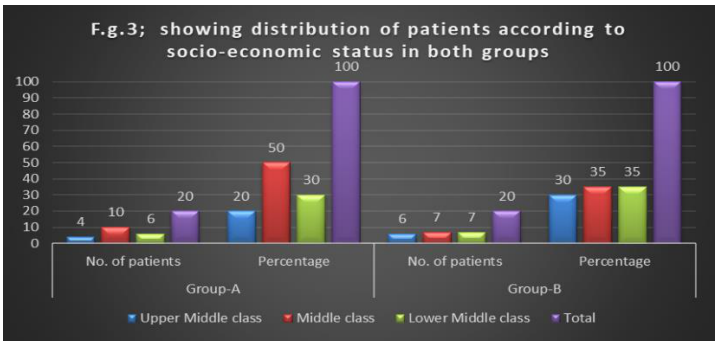
1. Number of subjects, age (Mean ±SD) and range of subjects.
2. Age-wise distribution of patients.
3. Socio Economic Status.
4. Mizaaj (Temperament wise) distribution of patients.
5. Distribution of Patient according to bleeding pattern and response to treatment.
6. Distribution of Patients according to Duration of MBL.
7. Distribution of Patients according to Symptoms of Diseases Before and After Treatment.
8. Distribution of Patients according to USG Findings before and after Treatment.
9. USG finding after treatment.
10. Changes in HB% finding after treatment.
11. Changes in Sr. Oestrogen finding after treatment.
12. Distribution of patients according to Therapeutic Response.



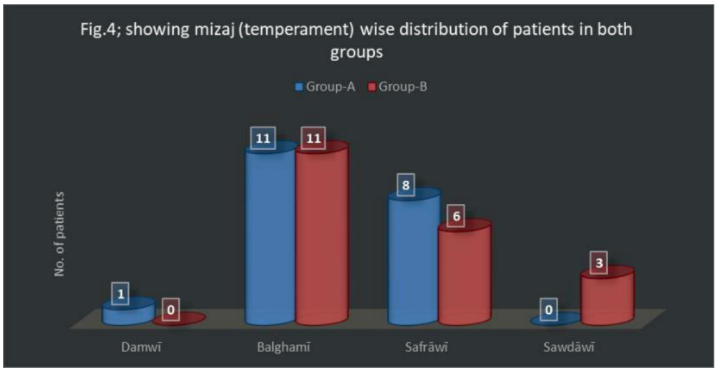
The graph, shows the observation in Group A, 20 patients were assessed with 39.2 ± 7.1 and within the range of 25 – 52 years. In Group B, 20 patients were assessed at 36 ± 6.8 years and within the range of 25 – 50 years.



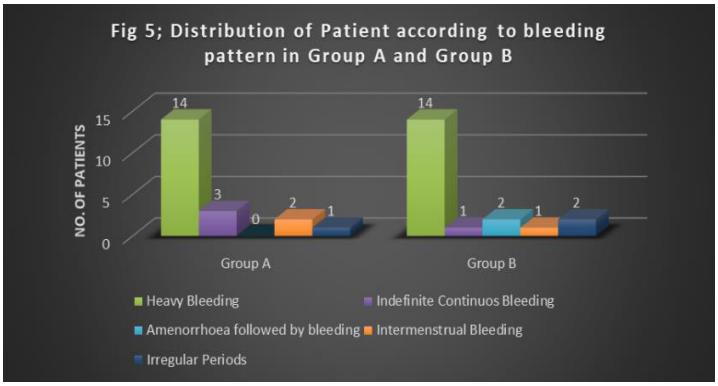
The graph, shows the incidence of endometrial hyperplasia is more common in the age group of 35-44 years that is (55%) and the lowest incidence is seen in the age group of 45-54yrs that is (10%).



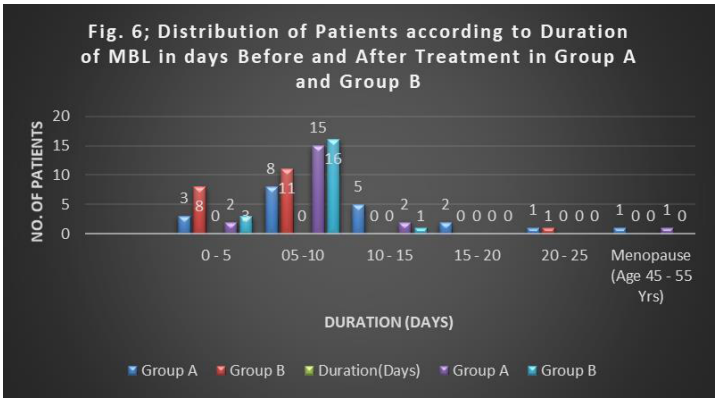
This graph, it has been observed that the highest incidence seen in 10 (50%) patients are from the middle class and the lowest incidence is seen in 4(20%) patients are from the upper middle class.



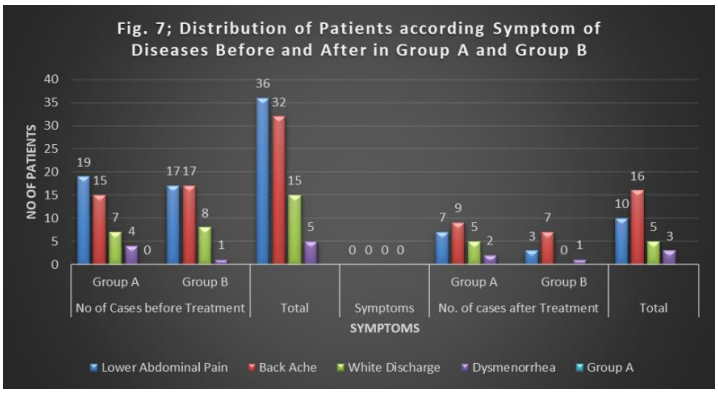
The graph, shows that it has been observed that the highest incidence seen in 11(55%) women were of phlegmatic temperament which is equal in percentage of both group A and group B and the lowest incidence seen in 1(5%) women have Damaw(Sanguine) temperament. The above study shows that there was no count of patients with Damawi Mizaaj in group B and Sawdawi Mizaaj in group A



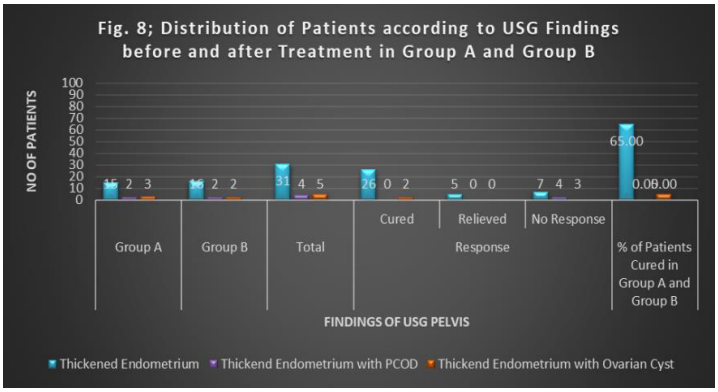
The graph, it can be inferred that endometrial hyperplasia can be encountered with any type of bleeding pattern.



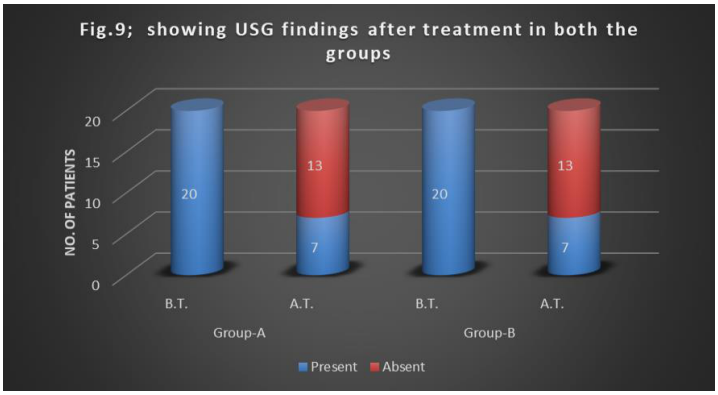
This graph, there was a significant reduction in the duration of menstrual blood loss after treatment. The maximum number of days of blood loss above 15-20 days is brought down to 6-9 days after treatment and the maximum number of days of menstrual blood loss is 5-10 days before treatment gradually decreases and is brought down to 5-6 days after treatment. Two patients came back with the complaints of heavy bleeding for more than 20 days after treatment. These patients had a good response with a normal cycle and a decrease in menstrual blood flow



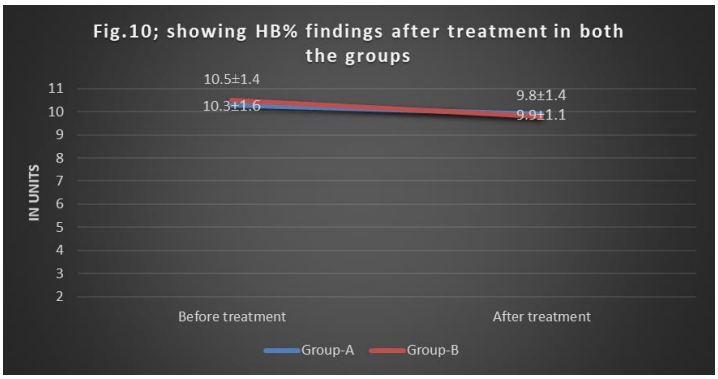
This graph, shows that the maximum number of patients with endometrial hyperplasia present with the complaints of lower abdominal pain 36(90%), backache 32(80%) white discharge 15(37.5%) and dysmenorrhoea 5 (12.5%).



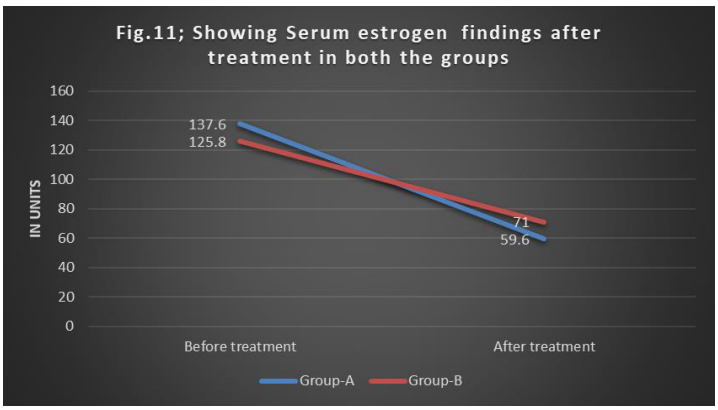
This graph, shows that the maximum number of patients with endometrial hyperplasia had thickened endometrium (endometrium thickness is more than 15mm) and the remaining cases of endometrial hyperplasia associated with other risk factors like PCOD and ovarian cyst.



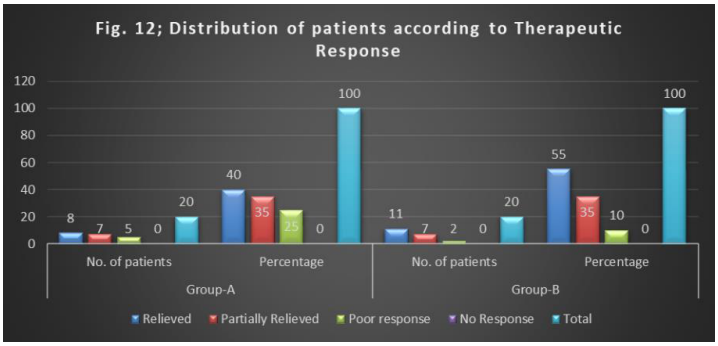
This graph, shows that before treatment 13 (65%) of patients had thickened endometrium in both groups A and B and after treatment the endometrium thickness gradually decreased to normal (7mm) tested after completion of treatment.



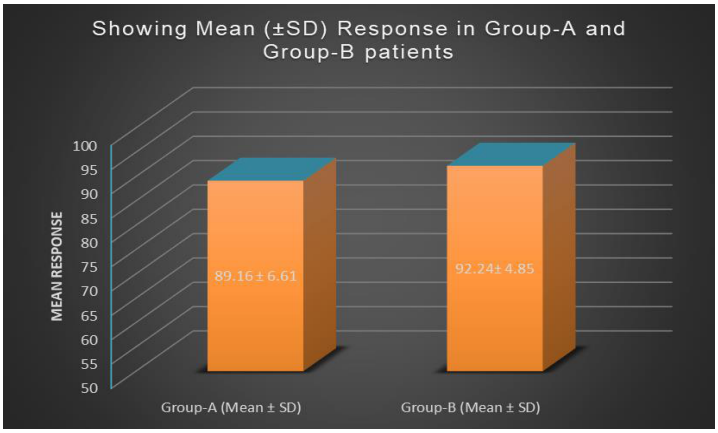
The graph, data shows that there is a mild reduction in HB % after treatment due to heavy menstrual loss



This graph, data shows the improvement of serum Estradial levels before and after treatment.



In the present study, 40 cases were registered with 20 in each group to assess the response of Group A and Group B Medicine. The above data shows that in Group A 8 Patients (40%) were Relieved, 7 Patients (35%) were Partially relieved and 5 patients (25%) had Poor response. In Group B, 11 patients (55%) were Relieved, 7 patients (35%) were partially relieved and 2 patients (10%) had Poor response



Figure/Graph 3

The above observation shows the therapeutic response in comparison between Group A and Group B. In the table, Mean response of Group A is 89.16 ± 6.61, and the Mean response of Group B is 92.24 ± 4.85. T-test is applied for the response. The value of P is < 0.05. Response of both Group A & B were observed almost equal but in comparison of response of Group B is slightly better than Group A. The t-test has been done to find out the significant difference between population means (2sample) or between the population mean and a hypothesized value (1 sample) i.e., the sample in group A and group B. The t-value measures the size of the difference relative to the variation in sample data T is simply calculated differences represented as units of standard error. The greater the magnitude of T (it can be either positive or negative) the greater the evidence against the null hypothesis that there is no significant difference. The closer T is to 0, the more likely there is no significant difference in the present study, after applying the t-test for standard analysis of results. It has been observed that the t value is not significant this assumed that the null hypothesis is rejected as the p valve is < 0.05.

Strength: The patients who received Unani treatment have shown good results and are satisfied. The patient can overcome the disease without any surgical process. All the coded medicines that were used have Astringent, Anti Inflammatory and Anti-bacterial properties. And there are no harmful side effects. With the high success rate and cost-effectiveness of the medicine, this can be easily made available to everyone.

Weakness: It is difficult to make quantitative predictions. It is more difficult to test hypotheses and theories with large participant pools. It generally takes more time to collect the data when compared to quantitative Research. Data analysis is often time-consuming. The results are more easily influenced by the researcher's basis sampling error occurs by chance, but it is reduced as the sample size increases. When non-random sampling is used this is not the case. All errors, other than sampling errors, are not sampling errors and can never be eliminated. The many sources on non-sampling errors include the following.

- Researcher's errors: Unclear definitions, reliability, and validity issues, data analysis problems, for example, missing data.
- Interviewer error: general approach, personal interviewer techniques, recording responses.
- Respondent error: Inability to answer, unwilling, not available, low response rate.
- Late Diagnosis of the disease.
- Refusal for admission.
- The patient is not willing to investigate.
- Lack of awareness in Unani Treatment.
- Irregular ups due to prolonged treatment.

RESULT AND DISCUSSION

After the careful study of parameters of the Benign Endometrial Hyperplasia and keeping the given complaints and complications research medicines were selected, formulated and divided into two groups. Group A and Group B. Treatment was given on an OP/IP basis in each group. Special coded medicine has been formulated, prepared and given to the patients for 12 days course in each cycle, and has been repeated for the next 3-4 cycles. All selected drugs were safe, and easily available, with no side effects. The drug's efficacy is better and

the patient tolerated the route of administration without Overwhelming side effects. The response of drugs was monitored after administration of drugs for 12 days course of treatment and it found that the patients showed improvement in subjective and objective parameters. Many patients show a good vitality sign towards this selected coded medicine.

After 3-4 cycles of treatment with pre & post-evaluation results were analysed statistically for significant improvement of subjective and objective parameters. The results were analysed by T-test, Chi square test, and standard deviation and tabulated out of 20 patients in Group A 8 patients (40%) were cured ,7 patients (35%) Partially relieved and 5(12.5%) patients were had poor response. Where as in Group B 11 patients (55%) cured and 7 patients (35%) were Partially relieved and 2(10%) patients had poor response. Via Graph/Fig No. 12.

The mean therapeutic response observed in group A is 89.16 ± 6.61 (SD) and the mean response of group B is 92.24 ± 4.85 (SD). Hence, Group B patients had improvement and good response when compared to Group A. However, Group A patients also had a good efficacy depending on the number of cured and partially relieved. Via Graph/Fig no 13.

CONCLUSION

After the detailed literary work, it comes to conclude that the maximum incidence is found in the age group of 35-44 years and it is more common in Multiparous Women and the maximum number of patients of this disease belongs to the middle-income group and it has been observed that endometrial hyperplasia is more common in patients of Balghami Mizaaj, because of the dominance of Khilt Balgham.

The maximum number of patients had Heavy bleeding, Lower Abdominal pain & back Ache. The drugs used for the trial in this study have the properties of Astringent, Coagulant, Aphrodisiac, Anti-inflammatory, Laxative, Digestive, and Analgesic.

From the present study, there was an overall improvement in the remission of symptoms, all the investigations were improved after 3 cycles of treatment. In Benign Endometrial Hyperplasia patients treated with 8 patients (40%) are cured in Group A, while 11 patients (55%) in Group B, 7 patients (35%) in Group A and 7 patients (35%) in group B are relieved and 5 patients (25%) had Poor response in Group A and 2 patients (10%) had Poor response in Group B. Total percentage cured in group A are 40% which comparatively less than group B is 55 % The drugs selected in test group have Astringent, Coagulant, Aphrodisiac, Anti-inflammatory, a laxative, digestive, analgesic effect which relieve the symptoms of Benign Endometrial Hyperplasia. These drugs were cost effective, easily available, and well tolerated by the patients without any side effects.

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